SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

Summary of Safety and Effectiveness

1.0 General Information

Device Generic Name:	Endovascular Prosthesis
Device Trade Name:	GORE VIABAHN® Endoprosthesis
Applicant's Name and Address:	W.L. Gore & Associates, Inc. 3450 West Kiltie Lane, P.O. Box 500 Flagstaff, AZ 86002
Date(s) of Panel Recommendation:	None
PMA Application Number:	P040037
Date of Notice of Approval to Applicant:	June 14, 2005

2.0 Indications for Use

The GORE VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery lesions with reference vessel diameters ranging from 4.8 to 7.5 mm.

3.0 Contraindications

Non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system.

4.0 Warnings and Precautions

See Warnings and Precautions in the labeling (Instructions for Use).

5.0 Device Description

The GORE VIABAHN® Endoprosthesis is a flexible, self-expanding endoluminal endoprosthesis consisting of an expanded polytetrafluoroethylene (ePTFE) lining with an external nitinol (NiTi = Nickel:Titanium) support extending along its entire length. The endoprosthesis is compressed and attached to a dual lumen polyethylene delivery catheter available in working lengths of 75 cm and 110 cm. The larger central catheter lumen is used for flushing and guidewire introduction. The smaller lumen contains elements of the deployment mechanism. The delivery catheter is attached to a three-port clear plastic adapter (hub assembly) that includes a central port for guidewire introduction, a second port for system flushing, and a third port for the deployment system. To facilitate accurate endoprosthesis placement, two radiopaque metallic bands are attached to the catheter shaft marking the ends of the compressed endoprosthesis. The GORE VIABAHN® Endoprosthesis is supplied sterile. The GORE VIABAHN® Endoprosthesis should not be resterilized.

6.0 Alternative Practices or Procedures

Alternative procedures include use of other commercially available stents, percutaneous transluminal angioplasty (PTA), medical management, atherectomy and bypass graft surgery.

7.0 Marketing History

The GORE VIABAHN® Endoprosthesis is currently available and marketed for vascular use in several markets worldwide, including the European Union, where the CE mark was obtained in 1996. These countries include the following: Argentina, Australia, Austria, Barbados, Belgium, Bermuda, Bolivia, Brazil, Chile, Columbia, Costa Rica, Dominican Republic, Denmark, El Salvador, Finland, France, Germany, Greece, Guatemala, Hong Kong, Iceland, India, Indonesia, Ireland, Italy, Luxembourg, Malaysia, Mexico, Netherlands, New Zealand, Norway, Panama, Paraguay, Peru, Philippines, Portugal, Singapore, Spain, Sweden, Switzerland, Thailand, Trinidad/Tobago, Uruguay, Venezuela, Vietnam, and United Kingdom. The GORE VIABAHN® Endoprosthesis has not been withdrawn from marketing for any reason relating to the safety or effectiveness of the device.

8.0 Potential Adverse Effects of the Device on Health

Adverse events (in alphabetical order) that may be associated with the use of a vascular stent/stent graft in the superficial femoral artery (in addition to those listed in Table 2) include:

- Aneurysm
- Arteriovenous (AV) fistula formation
- Dissection/intimal injury
- Drug reactions to antiplatelet agents/contrast medium
- Hypotension/hypertension
- Infection and/or pain at the access site
- Occlusion / restenosis of the treated vessel
- Pseudoaneurysm, femoral
- Puncture site complications
- Restenosis of stented segment
- Stent embolization
- Vessel perforation or rupture
- Vessel spasm

9.0 Summary of Preclinical Studies

9.1 Biocompatibility Testing

Biocompatibility Testing was conducted in accordance with Federal Good Laboratory Practices per 21 CFR §58. The GORE VIABAHN® Endoprosthesis is classified per ISO 10993 as an implant device with permanent blood contact; its delivery catheter was classified as an externally communicating device with limited exposure to circulating blood (less than 24 hours).

The GORE VIABAHN® Endoprosthesis is made of expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), and nickel-titanium alloy (nitinol). The delivery catheter is made of polyethylene and polycarbonate.

Table 1 summarizes the biocompatibility test results for the GORE VIABAHN® Endoprosthesis implant.

Table 1. Summary of GORE VIABAHN® Endoprosthesis Biocompatibility Testing

Category of Testing	Test	Results
Cytotoxicity	MEM Elution	Non-Cytotoxic
Sensitization	Kligman Maximization	Non-Sensitizing
Irritation/ Intracutaneous Toxicity	Intracutaneous Injection	Negligible Irritant
Acute Systemic Toxicity	Systemic Injection	No significantly greater biologic reaction than the controls.
Pyrogenicity	Rabbit Pyrogen	Non-Pyrogenic
Subchronic Toxicity	Canine Implant Study	No systemic effects observed.
Genotoxicity	S. typhimurium Reverse Mutation Assay	Non-Mutagenic
	CHO/HPGRT Forward Mutation Assay	Non-Mutagenic
	Chromosomal Aberration in Chinese Hamster Ovary Cells (CHO)	Non-Clastogenic
Implantation	Short Term Intramuscular Implantation (14 days)	Non-Toxic
	Short Term Intramuscular Implantation (28 days)	Slightly Toxic*
Hemocompatibility	Hemolysis	Non-Hemolytic
Chronic Toxicity	Canine Implant Study	No systemic effects observed.
Carcinogenicity	ISO 10993-1 states, "Carcinogenicity tests should be conducted only if there are suggestive data from other sources." There is no data known to Gore suggestive of carcinogenic risk. Therefore, carcinogenicity testing was not performed.	N/A

*Slight toxicity at 28 days is based on a toxicity rating of 1.03 due to increased tissue response at some of the implant sites. Implantation test used 1x1x10mm strip cut from a device for intramuscular implant. Cut wire ends were exposed during sample preparation that may have artifactually increased local tissue irritation. There were no clinical signs of toxicity in any of the animals tested. In another study the device was implanted intact in a more anatomically relevant location. The tissue response to the device was acceptable in this study.

Table 2 summarizes the biocompatibility test results for the delivery catheter.

Table 2. Summary of GORE VIABAHN® Endoprosthesis Delivery Catheter Biocompatibility Testing

Category of Testing	Test	Results
Cytotoxicity	MEM Elution	Non-Cytotoxic
Sensitization	Kligman Maximization	Non-Sensitizing
Irritation/ Intracutaneous Toxicity	Intracutaneous Injection	Negligible Irritant
Acute Systemic Toxicity	Systemic Injection	No significantly greater biologic reaction than the controls.
Hemocompatibility	Direct Contact	Non-Hemolytic
Pyrogenicity	Rabbit Pyrogen	Non-Pyrogenic

9.2 *In Vitro* Preclinical Testing

In vitro testing was performed on the GORE VIABAHN® Endoprosthesis and its delivery system and met the requirements of ISO 25539-1, Cardiovascular implants – Endovascular devices – Part 1: Endovascular prostheses. Many of the key attributes described in the ISO standard are relevant to the GORE VIABAHN® Endoprosthesis and its intended clinical application.

The in vitro testing was conducted to verify that the performance attributes of the GORE VIABAHN® Endoprosthesis are sufficient to minimize the risk of adverse events under anticipated clinical use conditions. Results obtained from the in vitro test regimen provide evidence demonstrating the safety and effectiveness of the device.

A summary of results is presented below for each of the in vitro tests. Table 3 summarizes test results associated with the functional requirements of the delivery system, and Table 4 summarizes test results related to functional requirements of the endoprosthesis or implant. The results presented in Tables 3 and 4 are based on testing performed on the sizes of the delivery systems and endoprostheses being approved in this PMA (6, 7, and 8mm Device Diameters).

The results of the in vitro testing demonstrate that the GORE VIABAHN® Endoprosthesis meets established functional requirements for endovascular prostheses. Furthermore, these data demonstrate the safety and effectiveness of the device which, consequently, is expected to perform as intended when used in accordance with its labeled indications.

Please refer to Tables 3 and 4 for a summary of the in vitro testing conducted on the device.

Table 3. Summary of *In Vitro* Test Results Related to Functionality of the GORE VIABAHN® Endoprosthesis Delivery System

Test	Relevant Functional Attribute	Summary of Test Results
Delivery Catheter Bond Strength	Ability to access the intended location Ability to deploy the implant Ability to retract delivery system	A total of 67 catheter bonds ere tested over three junctions. The minimum tensile force observed for each of the three critical catheter junctions (dual lumen to distal shaft, distal shaft to distal tip, lumen/strain relief to hub) exceeded the requirements for the respective bonds established in ISO 10555-1: Sterile, Single-use intravascular catheters. Additionally, the minimum expected tensile strength of any individual catheter bond is compliant with the relevant standard (ISO 25539-1: Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.2.1.2, 7.2.2.2, and 7.2.3.2 Bond strength.), and is sufficient to tolerate anticipated worst-case tensile loading of the GORE VIABAHN® Endoprosthesis delivery catheter.
Delivery Catheter Leak	Hemostasis	This test evaluated the leak resistance of the delivery catheter. No leakage occurred in any test when pressurized up to 20 atm. Conformance to the acceptance criteria of 1.5 atm and ISO 10555-1:1995(E) was demonstrated. All catheter components are inspected for this attribute.
Delivery Catheter Length	Ability to access the intended location	Measurements using a calibrated ruler were made on a total of 136 finished, 110cm long delivery catheters. All individual samples passed the acceptance criteria of 110 cm ± 2cm, and met the relevant standard, ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.3.5.2 and 7.3.6.3 Dimensional verification. Conformance to specifications is ensured through inspection requirements prior to being released for sale.
Delivery System Catheter Burst Pressure	Ability to access the intended location Hemostasis	Thirteen finished GORE VIABAHN® Endoprosthesis catheters were tested until the sample failed. All samples and the mean exceeded the established acceptance criterion. The relevant standard is ISO 25539-1: Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.2.5.3 Assessment of hemostasis. Statistical analyses demonstrated a very high likelihood that any individual catheter burst pressure is in excess of the acceptance criterion.
Delivery System Deployment Force	Ability to deploy the implant	A total of 104 finished GORE VIABAHN® Endoprosthesis systems were subjected to deployment force testing in a clinically relevant model according to the relevant standard, ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular

Test	Relevant Functional Attribute	Summary of Test Results
		Prostheses, Section: 7.2.2.10 Force to deploy. No individual or mean deployment force values were above the established acceptance criterion.
Delivery System Visibility	Ability to access the intended location Ability to deploy the implant Ability to retract delivery system Fluoroscopic visualization	Various tissue densities were simulated by using various thicknesses of aluminum plates in order to characterize delivery system fluoroscopic visibility. The in-vitro radiopacity evaluation of the GORE VIABAHN® Endoprosthesis demonstrates that the overall radiopacity is comparable to that of approved devices already in clinical use (e.g., EXCLUDER Bifurcated Endoprosthesis) under a range of simulated tissue densifications. Test results indicate that the delivery system and endoprosthesis can be visualized at various simulated tissue densities and have sufficient radiopacity for clinical use. Relevant standards included ISO 25539-1: Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.2.1.8, 7.2.2.11, 7.2.3.6, 7.3.1.3 Visibility; ASTM F640-79: Standard Test Methods for Radiopacity of Plastics for Medical Use.
Delivery System Profile	Ability to access the intended location Ability to retract delivery system Hemostasis	104 samples passed the acceptance criteria, 6 mm GORE VIABAHN Endoprosthesis, 8 Fr.; 7 & 8 mm GORE VIABAHN Endoprosthesis, 9 Fr. The relevant standard is: ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.2.1.3 Component dimension compatibility, 7.2.1.4 Dimensional verification, 7.2.1.6 Profile. Conformance to profile specifications is ensured through inspection.
Delivery System Simulated Use (Deployment Reliability)	Ability to access the intended location Ability to deploy the implant Ability to retract delivery system	All testing was performed in a clinically relevant model. Relevant standard includes ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.2.1.9, 7.2.2.12, 7.2.3.7, 7.3.1.4, 7.3.6.5 Simulated use. Evaluations included the following: successful deployment; accuracy; retraction force; and visual inspection. Appropriately sized hemostatic introducer sheaths, guidewires, and balloon catheters, were used according to the Instructions for Use in evaluating the overall deployment reliability of the GORE VIABAHN® Endoprosthesis System. All 118 samples deployed reliably, demonstrating acceptable retraction force, accuracy, and achieved stent apposition to the simulated vessel wall. The data demonstrate a very high likelihood that the GORE VIABAHN® Endoprosthesis will deploy correctly.

Test	Relevant Functional Attribute	Summary of Test Results
Delivery System Torquability	Ability to access the intended location Ability to deploy the implant Ability to retract delivery system	Torquing the delivery system is not required in order to deliver the device. Nevertheless, characterizations were conducted on approximately 136 samples which were deployed with approximately 360° of torque applied to the catheter shaft in a clinically relevant deployment model. All devices deployed successfully, demonstrating that torque does not impact deployment of the GORE VIABAHN® devices. The relevant standard is ISO 25539-1: Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.2.1.9 Simulated use.
Delivery System Trackability	Ability to access the Intended location	104 samples were characterized, utilizing devices across all diameters. Testing was conducted in a clinically relevant model using a contralateral approach to deliver the endoprosthesis to the target location. All tested GORE VIABAHN® Endoprosthesis delivery systems tracked well through a tortuous model over the recommended size guidewire. The relevant standard is ISO 25539-1: Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.2.1.12 Trackability.
Delivery Tubing Tensile Strength	Ability to access the intended location Ability to deploy the implant Ability to retract delivery system	Six samples of each type of tubing (distal shaft and dual lumen) were tested to characterize tensile strength. The lowest mean tensile strength result well exceeded the most stringent minimum bond strength requirement. Therefore, the delivery system tubing is expected to perform as intended in the clinical environment. The relevant standard is ISO 25539-1: Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.2.2.14, 7.2.3.9 Tubing tensile strength.
Deployment Knob/Line Assembly Tensile Strength	Ability to deploy the implant	Deployment knob/line assembly tensile strength was characterized through tensile testing of 142 finished knob/line assemblies. All values exceeded the established acceptance criteria. Therefore, the deployment knob/line assembly is expected to perform as intended in the clinical environment. The relevant standard is ISO 25539-1: Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.2.1.2, 7.2.2.2, and 7.2.3.2 Bond strength.

Table 4. Summary of *In Vitro* Test Results Related to Functionality of the GORE VIABAHN® Endoprosthesis

Test	Relevant Functional Attribute	Summary of Test Results
Endoprosthesis Bend Radius	Patency of the implant	All device diameters were characterized (n=18). The results show that the endoprosthesis is able to bend around relatively small diameters. Clinical experience demonstrates that the bend radius of the endoprosthesis is sufficient to allow the device to navigate through tortuous anatomy and conform to the host vessel anatomy. The relevant standards include ISO 25539-1, Cardiovascular Implants-Endovascular Devices-Part 1: Endovascular Prostheses, Sections: 7.3.5.3, 7.3.7.7, Flex/kink; ISO 7198:1998, Cardiovascular Implants-Tubular Vascular Prostheses, Section 8.9.
Endoprosthesis Burst Strength	Durability and integrity of the implant	The burst strengths of 14 GORE VIABAHN® Endoprostheses were determined. The mean burst strength, and all individual values are above the established acceptance criteria. The results were used to determine that the likelihood that any individual burst strength will be above the minimum acceptance criteria is very high. The relevant standards include ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.3.3.2 Burst/circumferential strength; ANSI/AAMI VP20-1994: Cardiovascular implants-Vascular Graft Prostheses, Section: 8.3.3.3. [Note: ANSI/AAMI VP20-1994 was adopted as ISO 7198:1998, which is referenced in ISO 25539-1 for burst testing.]
Endoprosthesis Diameter	Appropriate sizing of the implant	A total of 104 finished devices were measured for device inner diameter. All individual samples met the acceptance criteria established for each diameter. In addition, the data show with a very high degree of confidence that any individual sample will be within the acceptance criteria. The relevant standard is ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.3.5.2 and 7.3.6.3 Dimensional verification.
Endoprosthesis Integral Water Permeability	Permeability considerations	A total of 36 finished devices were characterized in a manner consistent with applicable standards. The integral water permeability for the GORE VIABAHN® Endoprosthesis was characterized. Clinical experience substantiates the adequacy of the integral water permeability of the device. The relevant standards include ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.3.4.3 Integral water permeability/ leakage; ANSI/AAMI VP20-1994, Section: 8.2.3. [Note: ANSI/AAMI VP20-1994 was adopted as ISO

Test	Relevant Functional Attribute	Summary of Test Results
		7198:1998, which is referenced in ISO 25539-1 for permeability testing.]
Endoprosthesis Length	Appropriate sizing of the implant	Devices were deployed and then measured. A total of 69 finished devices were measured post-deployment, representing all lengths. All devices met the established acceptance criteria by length. The relevant standard is ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.3.5.2 and 7.3.6.3 Dimensional verification.
Endoprosthesis Longitudinal Tensile	Durability and integrity of the implant	The longitudinal tensile strengths of 27 finished GORE VIABAHN® Endoprostheses were determined. All individual tensile strength values were above the established acceptance criteria. The likelihood that any individual tensile strength will be above the acceptance criteria is very high. The relevant standards include ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.3.3.6 Longitudinal tensile; ISO 7198: 1998, Section 8.3.2.
Endoprosthesis Magnetic Resonance Imaging Safety	MRI Compatibility	The results indicated that there were no magnetic field interactions (e.g., translational attraction or torque) at 1.5 Tesla. There was no substantial MRI-related heating, and image artifacts were characterized and shown to be relatively minor. Thus, GORE VIABAHN® Endoprosthesis is not anticipated to present a hazard or additional risk to an implant recipient or individual undergoing an MR procedure using an MR system operating with a shielded, static magnetic field of 1.5 Tesla or less. As such, the GORE VIABAHN® Endoprosthesis should be considered "MR safe" according to the specific conditions used for testing. The relevant standard is ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.3.8 Magnetic resonance imaging (MRI) compatibility.
Endoprosthesis Simulated Use (Deployment Reliability)	Ability to accurately deploy the implant Durability and integrity of the implant	All testing was performed in a clinically relevant model. The relevant standard includes ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.2.1.9, 7.2.2.12, 7.2.3.7, 7.3.1.4, 7.3.6.5 Simulated use. Evaluations included the following: successful deployment, accuracy, retraction force, and visual inspection. Appropriately sized hemostatic introducer sheaths, guidewires, and balloon catheters, were used according to the Instructions for Use in evaluating the overall deployment reliability of the GORE

Test	Relevant Functional Attribute	Summary of Test Results
		VIABAHN® Endoprosthesis System. All 118 samples deployed reliably, demonstrating acceptable retraction force, accuracy, and achieved stent apposition to the simulated vessel wall. The data demonstrate a very high likelihood that the GORE VIABAHN® Endoprosthesis will deploy correctly.
Endoprosthesis Visibility	Ability to accurately deploy the implant Fluoroscopic visualization	Various tissue densities were simulated by using various thicknesses of aluminum plates in order to characterize delivery system fluoroscopic visibility. The in-vitro radiopacity evaluation of the GORE VIABAHN® Endoprosthesis demonstrates that the overall radiopacity is comparable to that of approved devices already in clinical use (e.g., EXCLUDER Bifurcated Endoprosthesis) under a range of simulated tissue densifications. Test results indicate that the delivery system and endoprosthesis can be visualized at various simulated tissue densities and have sufficient radiopacity for clinical use. The relevant standards include ISO 25539-1: Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.2.1.8, 7.2.2.11, 7.2.3.6, 7.3.1.3 Visibility; ASTM F640-79.
Endoprosthesis Microscopic Determination of Porosity	Permeability considerations Patency of the implant	GORE VIABAHN® Endoprosthesis base tubes of ePTFE are identical regardless of diameter or length. Ten fibril length measurements were collected from each of two samples from each of three lots of material (60 data points overall). Results: All individual readings and the means of all readings met the acceptance criteria. The probability that any individual sample will meet the individual acceptance criteria is very high. The relevant standards include ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.3.4.2 Porosity, water permeability, and water entry pressure; ISO 7198: 1998, 8.2.1.3.
Endoprosthesis Radial Compression Strength	Fixation effectiveness of the implant Durability and integrity of the implant Appropriate sizing of the implant Patency of the implant	A total of 27 devices were tested across all diameter ranges. All devices tested met the established radial compression force acceptance criteria. In addition, the confidence that any individual radial compression strength will be above the acceptance criteria is very high for all sizes and configurations of the endoprosthesis. The relevant standard is ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Sections: 7.3.2.6 and 7.3.7.2 Radial outward force, 7.3.2.3 and 7.3.7.3 Crush resistance, 7.3.2.4 Local compression.

Test	Relevant Functional Attribute	Summary of Test Results
Endoprosthesis Stent Free Surface Area Calculation	Patency of the implant	Based on the length of wire used to wind the various sections of the stent, wire diameter, and device diameter at various percent compressions, the percentage of stent free surface area was calculated. The maximum change in stent-free surface area between the recommended vessel diameters for the various labeled diameters is 4% of the total surface area of the stent graft. Stent-free surface area calculations range between 72 and 77% at the minimum recommended vessel diameters and between 75 and 80% at the maximum recommended vessel diameters.
Endoprosthesis Finite Element Analysis (FEA)	Durability and integrity of the implant	Applicable guidance includes "Guidelines for Development and Use of Transluminally Placed Endovascular Prosthetic Grafts in the Arterial System" (Veith FJ et al., JVIR 1995; 6:477-492); ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.3.3.5.2 Stress-strain analysis. No acceptance criteria are applied to this FEA directly; however, the information generated serves as an analytical reference point for subsequent testing. The maximum, mean, and alternating strains were determined for all diameters of the GORE VIABAHN® Endoprosthesis as a function of worst case in-vivo oversizing and pulsatile loading conditions. The predicted strains are below the break strength of the Nitinol wire.
Nitinol Mechanical Properties & Material Analysis	Durability and integrity of the implant	1) Chemical Composition; 2) Surface Characteristics; 3) Thermomechanical Properties of the GORE VIABAHN® Endoprosthesis were compared to those of the EXCLUDER Bifurcated Endoprosthesis (P020004). Chemical Composition: The nitinol wire possesses the same material composition as the wire used to manufacture EXCLUDER Bifurcated Endoprostheses. Surface Characteristics: The surface condition of the nitinol wire is processed similarly, resulting in a surface condition and chemistry virtually identical to the EXCLUDER Bifurcated Endoprosthesis device. Thermomechanical Properties: Material is sampled, tested, and certified to ensure that the GORE VIABAHN® Endoprosthesis devices are superelastic at body temperature. Additionally, tensile testing has been conducted on representative wire samples to characterize the mechanical properties of the material. The results demonstrate that the tensile properties of the wire meet or exceed the established design specifications.

Test	Relevant Functional Attribute	Summary of Test Results
Endoprosthesis Pulsatile Fatigue	Fixation effectiveness of the implant Durability and integrity of the implant	Thirty-six finished endoprostheses were subjected to 10 years (380 million cycles). Acceptance criteria: The device must withstand 380 million cycles (equivalent to 10 years device life) of simulated physiologic loading without fatigue related wire fractures, device migration, failure of the ePTFE, or ePTFE/nitinol composite that would compromise device functionality (defined as luminal obstruction or puncture or tearing or the ePTFE material). Cyclic loading of the devices was performed to a calculated deflection between diastolic and systolic pressures to simulate physiological conditions. The test deflection was calculated to represent the highest strain experienced by the worst-case device diameter at the stated pressure differential. Devices were inspected for signs of stent wear and fracture. The inspection of the device at the end of the test cycle revealed that the device is expected to exhibit adequate mechanical integrity for at least 10 years. The relevant reference is "Guidelines for Development and Use of Transluminally Placed Endovascular Prosthetic Grafts in the Arterial System" (Veith FJ et al., JVIR 1995; 6:477-492).
GORE VIABAHN® Endoprosthesis Corrosion	Durability and integrity of the implant	The Nitinol wire components of the GORE VIABAHN® Endoprosthesis and the approved EXCLUDER™ Bifurcated Endoprosthesis (P020004) consist of the same specification material, follow identical electropolishing processes, and follow very similar thermal processing. The finished devices utilize virtually identical construction methods and are exposed to the same in vivo environment. For these reasons it is expected that both devices will exhibit similar corrosion performance. The approved EXCLUDER Bifurcated Endoprosthesis has demonstrated adequate corrosion resistance in previous testing and in clinical use; the GORE VIABAHN® Endoprosthesis can be reasonably expected to exhibit similar corrosion resistance that is clinically sufficient for the intended indication. The relevant standard is ISO 25539-1, Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.3.3.3 Corrosion.
GORE VIABAHN® Endoprosthesis Stent to Graft Attachment	Durability and integrity of the implant	The smallest and largest diameter GORE VIABAHN® Endoprostheses were selected to represent both the smallest and largest diameters of available devices. Three samples of each diameter were characterized. All test samples demonstrated the stent was attached to the graft. The relevant standard is ISO 25539-1,

Test	Relevant Functional Attribute	Summary of Test Results
		Cardiovascular Implants-Endovascular Guidance: Devices-Part 1: Endovascular Prostheses, Section: 7.3.3.8 Strength of stent/attachment system to graft bond.

9.3 Sterilization, Packaging, and Shelf-Life

The GORE VIABAHN® Endoprosthesis is sterilized using a validated ethylene oxide cycle in accordance with ANSI/AAMI/ISO 11135:1994 Medical Devices Validation and Routine Control of Ethylene Oxide Sterilization. The sterilization process has been shown to be acceptable for sterilization of the device to an SAL of 10^{-6}.

The packaging for the GORE VIABAHN® Endoprosthesis consists of four components: tray, primary pouch, secondary pouch, and box. The packaging is designed to protect the device from damage or alteration during customary conditions of processing, storage, handling, and distribution. The package is designed to maintain sterility of the device.

The GORE VIABAHN® Endoprosthesis has a three-year shelf-life.

9.4 *In Vivo* Preclinical Animal Studies

In vivo pre-clinical testing offered the opportunity to evaluate the GORE VIABAHN® Endoprosthesis by means not readily available with *in vitro* methods. W.L. Gore & Associates, Inc. ("GORE") has conducted four preclinical *in vivo* studies to evaluate the performance of the GORE VIABAHN® Endoprosthesis. The purpose of the preclinical animal studies was to evaluate the safety and performance of the GORE VIABAHN® Endoprosthesis in an *in vivo* environment that modeled the clinical application. The studies were intended to demonstrate the safety of the device prior to clinical use.

The canine model was used for assessment of the delivery system to:

- successfully access the target site
- accurately deploy the endoprosthesis and be able to easily remove the catheter from the vasculature

The canine model was also used to assess the following aspects of the implantable endoprosthesis:

- test the ability of the endoprosthesis to resist migration
- evaluate device functionality
- determine the biological response to the implanted endoprosthesis

In selecting the appropriate animal model, an effort was made to evaluate device performance in models that would demonstrate performance attributes in a clinically meaningful fashion. In conducting the preclinical animal studies for the GORE

VIABAHN® Endoprosthesis, the same introduction and deployment methods that would be used in the clinical setting were modeled as much as possible. Devices used in these in vivo studies are representative of the finished product. Standard imaging techniques such as angiography and intravascular ultrasound (IVUS), which provide visualization and localization of the device, were used, as appropriate, in these studies. Gross inspection and histological assessment were used to evaluate the explanted device. Successful device implantation included the ability to visualize and accurately deploy the device with techniques similar to those required in animals, and firm fixation of the device at the site of original deployment. Additional measures of evaluation included the absence of device migration, sustained luminal patency, and acceptable host tissue response and device incorporation.

A total of 73 devices were implanted into 35 different canines in 4 different studies. With the exception of acute animal studies, the animals were alive from 10 – 365 days. Overall conclusions from these studies demonstrated the following:

- The delivery system was acceptable to the implanting surgeon and that the device can be deployed properly and accurately with minimal difficulty or complications.
- No twisting or kinking of the device was observed after implantation.
- The majority of the devices remained patent during the in-life period.
- Stenosis of the device over time was minimal.
- There was minimal inflammation response caused by a device or device implant.
- No adverse biological reactions to the device were observed.
- The occurrence of thrombosis in the device was low.
- Healing response to the device was good.
- In vivo testing showed the endoprosthesis to be safe and to function as an endovascular device.

10.0 Summary of Clinical Studies

A total of 244 cases were treated at 25 U.S. investigational sites. The purpose of the study was to compare the safety and effectiveness of the GORE VIABAHN® Endoprosthesis to percutaneous transluminal angioplasty (PTA) in patients with chronic lower limb ischemia or chronic lifestyle altering claudication due to superficial femoral artery (SFA) atherosclerotic disease. A total of 241 patients or 244 cases (limbs) were treated in the study. For the purposes of this document, use of the term "cases" refers to treated limbs. Each site was permitted up to two training cases. A total of 47 training cases were performed; 197 cases were randomized with 100 assigned to PTA and 97 to the GORE VIABAHN® device.

Study Endpoints: The primary endpoint was primary patency of the treated vessel at 12-months. Secondary endpoints included clinical success, the adverse event rate, as well as changes in the Ankle-Brachial Index (ABI), clinical success, and limb ischemia score. For purposes of analysis, patency of the treated vessel and technical success were redefined to more accurately reflect current clinical practices. The original endpoint definition of patency included the composite variables of technical success and treatment success of the treated vessel. Based on current clinical practices, the definition of patency was redefined as "no target revascularization procedure and no evidence of restenosis or occlusion within the originally treated vessel based on a centrally-read CFDU." The redefined endpoints of patency and technical success and the other originally defined endpoints were used in the interpretation of the clinical

data. Definitions for each of the endpoints are provided below. Endpoints were also analyzed on an intent-to-treat (ITT) and per protocol (PP) basis. The ITT population included all randomized cases. The PP population consisted of a subset of the ITT population for which the assigned VIABAHN or PTA procedure was successfully administered and for whom no significant protocol deviations were observed.

Primary patency of the target vessel: A composite of treatment success, technical success and freedom from interrupted blood flow or revascularization to the treated vessel.

Treatment success: Completion of the assigned procedure without a major adverse event, stenosis < 50% and patency by Color Flow Doppler ultrasound (CFDU).

Technical success: Treatment success and at 30 days no major adverse event and improvement in segmental limb pressure of 0.15.

Clinical success: Improvement of at least one category using the Rutherford Clinical Status Scale (1997). Cases with tissue loss must have improved by at least two categories and reach the level of claudication to be considered improved.

Redefined technical success: Successful completion of the assigned treatment and post-treatment angiographic results demonstrating less than 30% residual stenosis.

Redefined patency of the target vessel: No target vessel revascularization (TVR) procedure and no evidence of restenosis or occlusion within the originally treated vessel based on a centrally-read CFDU (occlusion and restenosis are defined as no color flow or at least a doubling of focal systolic velocity respectively).

Patients Studied: Eligible patients were candidates for PTA with *de novo* or restenotic atherosclerotic or occlusive lesion(s) of the superficial femoral artery causing either chronic lifestyle altering claudication or chronic lower limb ischemia and who had a percent diameter stenosis of ≤ 50% following the initial PTA. Stenotic or occlusive lesion(s) originating in the superficial femoral artery were ≤ 13 cm in length and ranging from 4.5 mm to 12 mm in diameter.

Methods: Patients eligible for the study were prospectively randomized to treatment with the GORE VIABAHN® Endoprosthesis or PTA. Baseline angiography was performed pre-PTA, post-PTA and post-procedure. Duplex Color Flow Doppler Ultrasound (CFDU) and clinical assessments were completed at discharge, and 1, 6 and 12 months post-procedure. For redefined patency of the target vessel, centrally read CFDU videotapes were utilized. Occlusion and restenosis were defined as no color flow or at least a focal doubling of peak systolic velocity (PSVR) respectively.

Results: The study was originally designed to enroll 415 patients. However, due to clinical study design and endpoint definitions, the Sponsor terminated the study prior to completion of enrollment. Technical success and primary patency were redefined as described above to be more clinically relevant. No safety issues were involved in the termination decision. Sites were instructed to follow their patients through the 1-year exam with optional follow-up at 2-years. Follow-up compliance at the 12-month visits was 69% (69/100) for the PTA group and 79% (114/144) for the GORE VIABAHN® device group.

Baseline characteristics of the two treatment groups were similar (Table 5).

Table 5. Summary of Pre-procedure Characteristics

VARIABLE	PTA (N=100)	GORE VIABAHN® All Cases (N=144)	GORE VIABAHN® Randomized Only (N=97)
Age (yrs) , mean ± SD	66.9 ± 9 5	66.7 ± 10.1	67.2 ± 9 7
Males	70 (70.0%)	114 (79.2%)	80 (82.5%)
History of smoking	51 (51.0%)	73 (50.7%)	45 (46.4%)
History of MI	30 (30.0%)	38 (26.4%)	23 (23.7%)
History of diabetes mellitus	34 (34.0%)	49 (34.0%)	36 (37.1%)
ABI, mean ± SD	0.67 ± 0.18	0.73 ± 0.18	0.74 ± 0.17
Reference Vessel Diameter (mm), mean ± SD	5.6 ± 0.8	5.6 ± 0.6	5.6 ± 0.6
Mean Luminal Diameter (mm), mean ± SD	1.1 ± 1.0	1.2 ± 1.0	1.3 ± 1.0
Lesion length (cm), mean ± SD	6.7 ± 3.7	7.3 ± 3.6	7.3 ± 3.6
Percent diameter stenosis (%), mean ± SD	80.9 ± 17.1	77.7 ± 18.2	77.1 ± 17.5
Occlusion	29 (29.0%)	37 (25.7%)	20 (20.6%)

As shown in Table 6, there were no differences between the GORE VIABAHN® Endoprosthesis and PTA groups in the rates of primary patency of the treated vessel or technical success. The GORE VIABAHN® device cases showed higher rates of treatment success and clinical success at 12-months than PTA. For redefined patency of the target vessel and technical success, the GORE VIABAHN® device group had higher mean rates. A further breakdown of redefined patency by lesion length resulted in benefit for GORE VIABAHN® device cases with longer lesions (Table 8). Similarly, redefined technical success for GORE VIABAHN® device cases with longer lesions (3-12 cm) was better than those in the PTA group (Table 9).

As shown in Table 7, the GORE VIABAHN® device group demonstrated a trend towards greater clinical improvement at 6 and 12 months, as assessed with the clinical status score. There were no differences between groups in the mean change from baseline for the resting ABI and limb ischemia scores.

Gender bias

A higher proportion of males (75%) than females (25%) were included in the trial, which is reflective of the distribution of the disease in the population. Females did not demonstrate as pronounced an advantage as males with respect to treatment success, clinical success, redefined patency, and redefined technical success.

The early and late adverse event rates for males and females were comparable. It was noted that GORE VIABAHN® device male cases had a higher rate of early adverse events (major or minor) than PTA male cases (31.6% GORE VIABAHN® device and 15.7% PTA). The difference is a result of a higher proportion of reports of minor pain in the leg, groin or back. The rates of adverse events for all other types of complications are comparable between groups for males.

Table 6. Summary of Effectiveness Outcomes

Effectiveness Measures	PTA	GORE VIABAHN® All Cases	GORE VIABAHN® Randomized Only
ITT Population	(N=100)	(N=144)	(N=97)
12-month Outcomes:			
Primary Patency	45%	51%	50%
Clinical Success	69%	84%	81%
Treatment Success	84%	94%	94%
Technical Success	61%	65%	59%
Redefined:			
Patency at 12-months	40%	62%	65%
Technical Success	66%	94%	95%

Table 7. Summary of Clinical Outcomes

Clinical Measures	PTA	GORE VIABAHN® All Cases	GORE VIABAHN® Randomized Only
ITT Population	(N=100)	(N=144)	(N=97)
Clinical Status: Improved			
1-month	89%	88%	87%
6-months	72%	84%	85%
12-months	75%	84%	82%
Change in Limb Ischemia (means)			
1-month	-1.73	-1.64	-1.61
6-months	-1.36	-1.55	-1.61
12-months	-1.45	-1.72	-1.62
Change in Ankle Brachial Index (means)			
Discharge	.28	.25	.24
1-month	.29	.24	.22
6-months	.18	.22	.19
12-months	.22	.22	.19

Clinical Status Score: Rutherford Scale +3, +2, +1, 0, -1, -2, -3
Limb Ischemia: Rutherford 0 – 6

Table 8. Summary of Redefined Target Vessel Patency by Lesion Length – ITT Population

Variable (N= PTA/N=GORE All Cases/N=GORE Randomized Only)	PTA	GORE VIABAHN® All Cases	GORE VIABAHN® Randomized Only
All (100/144/97)	40%	62%	65%
Treatment Segment Length			
≤ 3 cm (21/23/19)	66%	67%	65%
3 – 6 cm (28/39/19)	39%	56%	64%
6 – 9 cm (21/37/29)	28%	66%	67%
9 – 12 cm (24/29/21)	38%	67%	68%
> 12 cm (6/16/9)	17%	54%	56%

Table 9. Summary of Redefined Technical Success by Lesion Length – ITT Population

Variable (N= PTA/N= GORE All Cases/N=GORE Randomized Only)	PTA	GORE VIABAHN® All Cases	GORE VIABAHN® Randomized Only
All (100/144/97)	**66.0%**	**94.4%**	**94.8%**
Treatment Segment Length			
≤ 3 cm (21/23/19)	90.5%	91.3%	94.7%
3 – 6 cm (28/39/19)	60.7%	94.9%	94.7%
6 – 9 cm (21/37/29)	71.4%	94.6%	93.1%
9 – 12 cm (24/29/21)	45.8%	93.1%	95.2%
> 12 cm (6/16/9)	66.7%	100.0%	100.0%

Adverse Events (AE's)

There was a slight trend toward increased early adverse event rates in the GORE VIABAHN® device groups compared with the control group; the difference in the early adverse event rates is small and does not raise safety concerns (Table 10). For complications especially pertinent to the procedure and device, the rates of occurrence of major amputation, bleeding events, vascular complications, and distal embolization were clinically indistinguishable. The rate of major device malfunction was low. The rate of mortality was low in the study. One GORE VIABAHN® device patient (0.7%) with significant co-morbidities died during the original hospitalization. The rate of freedom from TVR was comparable between groups.

Table 10. Summary of Safety

Safety Measures ITT Population	PTA (N=100)	GORE VIABAHN® All Cases (N=144)	GORE VIABAHN® Randomized Only (N=97)
Major Early AEs:			
Any Major AE	4.0%	7.6%	8.2%
Amputation	1.0%	0.0%	0.0%
Bleeding complications	0.0%	0.0%	0.0%
Vascular complications	0 0%	1.4%	1.0%
Distal embolization	1.0%	3.5%	4.1%
Device malfunction	0.0%	1.4%	2.1%
Late AE (any major)	13%	12.5%	8.2%
Mortality within 30-days	0.0%	0.7%	1.0%
TVR free rate at 12 months	79%	75%	80%

Amputation: Surgical removal of any portion of the involved leg, foot or toes.
Bleeding complication: Procedural blood loss of more than 1000 ml or post procedure related bleeding that occurs after the subjects left the OR resulting in need for transfusion.
Vascular complication: arterial rupture, artery injury, AV fistula, dissection, erosion through the vessel wall, false aneurysm, or puncture site bleeding.
Distal embolization: thrombus or embolism distal to the original treatment site.
TVR: target vessel revascularization.

Tables 11 and 12 reflect a complete description of adverse events observed in the clinical study of the GORE VIABAHN® Endoprosthesis.

Table 11. Major Adverse Events through 12 Months
Number (%)

AE Category ITT Population	Early (≤ 30 days)			Late (> 30 days to 12-months)		
	PTA (N=100)	GORE VIABAHN All Cases (N=144)	GORE VIABAHN Randomized Only (N=97)	PTA (N=100)	GORE VIABAHN All Cases (N=144)	GORE VIABAHN Randomized Only (N=97)
Any Major Event*	4 (4.0)	11 (7.6)	8 (8.2)	13 (13.0)	18 (12.5)	8 (8.2)
Amputation	1 (1.0)	0 (0.0)	0 (0.0)	1 (1.0)	2 (1.4)	1 (1.0)
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bowel ischemia/ obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contrast / medication reaction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac	3 (3.0)	1 (0.7)	1 (1.0)	8 (8.0)	11 (7.6)	4 (4.1)
Distal embolization	1 (1.0)	5 (3.5)	4 (4.1)	1 (1.0)	0 (0.0)	0 (0.0)
Hematoma	1 (1.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Infection	0 (0.0)	1 (0.7)	1 (1.0)	1 (1.0)	1 (0.7)	0 (0.0)
Neurovascular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain (leg/groin/back)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	1 (0.7)	1 (1.0)
Paraparesis/paraplegia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Post implant syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary	0 (0.0)	1 (0.7)	1 (1.0)	1 (1.0)	0 (0.0)	0 (0.0)
Renal failure	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.4)	2 (2.1)
Stroke/TIA	0 (0.0)	1 (0.7)	1 (1.0)	1 (1.0)	4 (2.8)	1 (1.0)
Vascular	0 (0.0)	2 (1.4)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Deep Venous Thrombosis	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.0)	0 (0.0)	0 (0.0)

*Any Major Event includes the following: a) requires therapy, minor hospitalization (< 48 hours), b) requires major therapy, unplanned increase in level of care, prolonged hospitalization, c) permanent adverse sequelae, or d) death.

Table 12. Minor Adverse Events through 12 Months
Number (%)

AE Category ITT Population	Early (≤ 30 days)			Late (> 30 days to 12-months)		
	PTA (N=100)	GORE VIABAHN All Cases (N=144)	GORE VIABAHN Randomized Only (N=97)	PTA (N=100)	GORE VIABAHN All Cases (N=144)	GORE VIABAHN Randomized Only (N=97)
Any Minor Event*	17 (17.0)	33 (22.9)	24 (24.7)	2 (2.0)	6 (4.2)	5 (5.2)
Amputation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bleeding	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bowel ischemia/ obstruction	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Contrast / medication reaction	4 (4.0)	1 (0.7)	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac	2 (2.0)	4 (2.8)	3 (3.1)	0 (0.0)	1 (0.7)	1 (1.0)
Distal embolization	2 (2.0)	6 (4.2)	4 (4.1)	0 (0.0)	1 (0.7)	1 (1.0)
Hematoma	7 (7.0)	13 (9.0)	12 (12.4)	0 (0.0)	1 (0.7)	1 (1.0)
Infection	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neurovascular	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain (leg/groin/back)	3 (3.0)	14 (9.7)	10 (10.3)	3 (3.0)	3 (2.1)	1 (1.0)
Paraparesis/paraplegia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Post implant syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pulmonary	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Renal failure	1 (1.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Stroke/TIA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular	3 (3.0)	7 (4.9)	6 (6.2)	0 (0.0)	1 (0.7)	1 (1.0)
Other**	1 (1.0)	4 (2.8)	3 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)

*A Minor Adverse Event is an adverse event that does not meet the definition of a Major Adverse Event. See Table 11.

** Other includes the following: VIABAHN: Thigh pain, focal slight intimal defect distal to the stent graft, nausea, generalized purities without rash. PTA: After fem stop was applied to right groin, patient experienced vasovagal reaction without hypotension.

Patient Death Summary

One GORE VIABAHN® device subject died 16 days after the procedure. This subject had significant co-morbidities and sepsis was reported as the cause of death.

One GORE VIABAHN® device subject and three PTA subjects died more than 30 days but less than 12 months post-procedure. The GORE VIABAHN® device patient died approximately 6 months post-procedure. The exact date and cause are unknown. Two PTA subjects died due to a myocardial infarction (MI) and the third due to a pulmonary embolus and MI.

In the second year of follow-up, two GORE VIABAHN® device subjects died. One died with secondary heart failure due to chemotherapy and radiation therapy for lung cancer. The other subject had a history of coronary artery disease (CAD), congestive heart failure (CHF), MI, and diabetes. This subject developed gangrene and had an above the knee amputation; the patient expired several days later.

Observed Device Malfunctions

Device malfunctions were observed in eight cases (10 incidents). Those involving the delivery catheter included four attributed to difficulty removing the delivery device and two catheter tip breakage. One involved a deployment failure or malfunctioning stent, one introduction with device kinking, one balloon catheter rupture during post-dilation and one guidewire tip breakage.

10.1 Selected Publications

Additional clinical experiences using the GORE VIABAHN® Endoprosthesis in the superficial femoral artery have been reported in the literature. These reports provide additional long-term performance information regarding the safety and effectiveness of the device for the superficial femoral artery indication. Selections from that literature are included below (See Tables 13 and 14) and the literature citations are provided at the end of this section. These studies report patency rates comparable to those reported in this PMA. The reported technical success was 100%. Adverse events reported in the literature were minor and occurred acutely. The rate of distal embolization reported in the clinical trial in Table 10 is comparable to the range of rate reported in the literature.

TABLE 13 – Summary of Effectiveness (Patency) from Selected GORE VIABAHN® Endoprosthesis Literature

Author Yr. Tx. Seg.	N (Limbs) / Ave. Length (cm)	Primary Patency (years)						Patency Definition
		0.5	1	2	3	4	5	
Bleyn 2004 SFA	67 / 14.3	84%	82%	73%	68%	54%	47%	Patent by duplex ultrasound
Saxon 2004 SFA	42 / >10	90%	86%	79%	79%	70%	--	No occlusion and absence of 50% restenosis as determined by duplex ultrasound (PSVR < 2.0)
Bauermeister 2001 SFA	35 / 22	79%	73%	--	--	--	--	No occlusion and absence of 50% restenosis as determined by duplex ultrasound

Author Yr. Tx. Seg.	N (Limbs) / Ave. Length (cm)	Primary Patency (years)						Patency Definition
		0.5	1	2	3	4	5	
Lammer 2000 SFA	80 / 13.8	90%	79%	--	--	--	--	No occlusion and absence of 50% restenosis as determined by duplex ultrasound (PSVR < 2.5)
Ave.	**224 / 15.0**	**86%**	**80%**	**76%**	**73.5%**			

Table 14 -Summary of Safety (Adverse Events) from Selected GORE VIABAHN Endoprosthesis Literature

Author Yr Tx. Seg.*	N (Limbs) / Ave. Length (cm)	Distal Emboli-zation	Hema-toma	Implant Syndrome[2]	Acute Throm-bosis	Infection	Con-version	Amp.	Death
Tarantini 2004 SFA	28 / 29	NR*	NR	NR	NR	NR	NR	11%[1]	0%
Saxon 2004 SFA	42 / >10	7%[2] (minor) 7% (req. tx.)	NR	15%[3]	5%	NR	NR	NR	NR
Bleyn 2004/2002 SFA	67 / 14.3	27%[4]	9%[5]	NR	--[4]	NR*	NR	1%	1%[6]
Jahnke 2003 SFA Fem Pop	52 / 8.5	7.7%[7]	13.5%	5.8%[8]	2%	NR	0% in first 30 days	NR	NR
Bauermeister 2001 SFA	35 / 22	NR	NR	NR	3%	NR	NR	NR	NR
Lammer 2000 SFA	80 / 13.8	3%	2%	NR	4%	0%	0%	0%	0%
TOTAL	304 / 16.2								

*Treated Segment. SFA refers to superficial femoral artery; Fem Pop refers to Femoropopliteal artery.

**NR = None Reported for a particular adverse event, although adverse events are discussed within the publication. Fields with -- reflect papers without any discussion of adverse events generally.

[1] "There were three amputations: one for graft failure and two for progressive gangrene despite graft patency."

[2] "Angiography detectable embolization was seen in 14% (6/42) of treated limbs in our series. However 3 of these cases were felt to be clinically insignificant small vessel occlusions, they caused no adverse event clinical sequelae and one resolved spontaneously. Clinically significant embolization occurred in 7% (3/42) of treated limbs. The majority of embolizations were detected in patients who had an endograft placed following catheter-directed thrombolysis for acute arterial occlusions. Further lysis or suction embolectomy has been universally successful in sever/symptomatic cases."

[3] Post Implantation Syndrome is described as localized thigh pain occurring for one to two weeks following device placement and appears to be related to excessive oversizing of touch-up ballooning of the VIABAHN Endoprosthesis. "The pain started immediately after placement and lasted 1 to 2 weeks, occasionally requiring narcotic analgesia."... "We suspect the pain is because of over-expansion of the vessel by the endoprosthesis at initial dilation. We now dilate the device to the size of the normal vessel...Since we have stopped substantially over-dilating the vessel, pain postprocedure has been much less of an issue."

[4] Distal embolization and acute thrombosis are reported together. "Peripheral emboli or postoperative thrombosis was diagnosed in 18 (26.9%) patients, but only 1 was resistant to immediate thrombolysis." "The Hemobahn endoprosthesis was implanted percutaneously without systemic heparinization."
[5] "Conservativley treated hematoma"
[6] "Death due to a retroperitoneal hematoma in combination with poor cardiopulmonary function."
[7] "all successfully treated by aspiration thrombectomy and/or short-term loca fibrinolysis,"..."All cases of distal embolization occurred in patients who initially presented with total occlusions."..."were without clinical sequelae"
[8] "minor groin hematoma in seven patients"..."were without clinical sequelae"

10.2 Literature Citations for Selected Publications

Tarantini F.A., et al., Use of Expanded Polytetrafluoroethylene Covered Endoprosthesis for the Treatment of Infrainguinal Arterial Occlusive Disease. Abstract presented at the Eastern Vascular Society (EVS) 18th Annual Meeting, April 29-May 2, 2004, Philadelphia, PA. page 62.

Bleyn J, Schol F, Vanhandenhove I, Vercaeren P, Marien C. in Controversies and Updates in Vascular and Cardiac Surgery, Chapter 14. Edizioni Minerva Medica, Torino, Italy 2004.

Bleyn J, Goverde P. Hemobahn in Superficial Femoral Artery Occlusive Disease: Long-term Results. Abstract presented at the 15th Annual International Congress. Feb. 10-14, 2002, Scottsdale, AZ page X-7.

Saxon RR, Coffman, MJ, Gooding JM, and Ponec DJ. Endograft Use in the Femoral and Popliteal Arteries. Techniques in Vascular and Interventional Radiology 2004; 7(1): 6-15.

Jahnke, T et al., Hemobahn Stent-Grafts for Treatment of Femoropopliteal Arterial Obstructions: Midterm Results of a Prospective Trial" Journal of Vascular and Interventional Radiology 2003; 14:41-51.

Bauermeister G. Endovascular stent-grafting in the treatment of superficial femoral artery occlusive disease. Journal of Endovascular Therapy 2001; 8:315-320.

Lammer J, Dake MD, Belyn J, et al. Peripheral Arterial Obstruction: Prospective Study of Treatment with a Transluminally Placed Self-Expanding Stent Graft. Radiology 2000; 27:95-104.

11.0 Conclusions Drawn from the Studies

The preclinical studies indicate that the GORE VIABAHN® Endoprosthesis meets or exceeds safety and performance specifications.

The randomized clinical trial results and information drawn from the published literature provide reasonable assurance that the GORE VIABAHN® Endoprosthesis is safe and effective when used in accordance with its labeling. Multicenter, randomized clinical study results demonstrated that the GORE VIABAHN® device when compared to PTA resulted in higher rates of treatment success, technical success, and 12-month patency as defined by current clinical standards. Likewise, the GORE VIABAHN® device cases demonstrated a trend towards greater improvement for clinical success and clinical status scores. Other primary efficacy parameters were comparable

between the GORE VIABAHN® Endoprosthesis and PTA groups. Multicenter clinical data show that the rates of adverse events for the GORE VIABAHN® Endoprosthesis group were comparable to the PTA group.

The preclinical testing information and the randomized clinical trial results provide valid scientific evidence and reasonable assurance that the GORE VIABAHN® Endoprosthesis is safe and effective when used in accordance with its labeling.

12.0 Panel Recommendation

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Cardiovascular Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

13.0 CDRH Decision

FDA issued an approval order on June 14, 2005.

The applicant's manufacturing facility was inspected and was found to be in compliance with the Quality System Regulation (21 CFR 820).

Approval of this PMA application was predicated partly on a qualitative clinical assessment of the results of the randomized clinical trial rather than quantitative statistical inferences drawn from the clinical data. The clinical trial protocol was originally approved in 1996 and the study design was changed after enrollment had begun, with the concurrence of FDA; as a result, the study design did not meet our current expectations and no quantitative statistical inferences or conclusions could be reached. FDA's understanding of the clinical environment for devices of this type has advanced since this clinical study protocol was approved in 1996, and FDA's expectation for future approvals is that marketing applications for similar indications will be accompanied by clinical data from which quantitative statistical inferences can be drawn.

14.0 Approval Specifications

Directions for use: See the labeling.

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Events in the labeling.

Postapproval Requirements and Restrictions: See approval order.